

Serial No.

57. A recombinant polynucleotide according to claim 55 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

58. A recombinant polynucleotide according to claim 54 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

59. A recombinant polynucleotide according to claim 58 in which the promoter active in the prostate is a PSM promoter.

60. A recombinant polynucleotide according to claim 54 in which the regulatory element is an enhancer element.

61. A recombinant polynucleotide according to claim 66 in which the enhancer element comprises:

(a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or

(b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

62. A recombinant polynucleotide according to claim 60 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

63. A recombinant polynucleotide according to claim 60 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

64. A recombinant polynucleotide according to claim 54 in which the polynucleotide comprises two or more regulatory elements derived from intron 3 of the PSM gene.

65. A recombinant expression cassette comprising at least one regulatory element derived from intron 3 of the PSM gene, a promoter, and an insertion site into which a coding sequence is optionally inserted, the insertion site being adjacent to and downstream of the promoter.

66. A recombinant expression cassette according to claim 65 in which the regulatory element is located adjacent to the promoter.

67. A recombinant expression cassette according to claim 65 in which the regulatory element is upstream of the promoter.

68. A recombinant expression cassette according to claim 65 in which the regulatory element is an enhancer element.

69. A recombinant expression cassette according to claim 68 in which the enhancer element comprises

(a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or

(b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

70. A recombinant expression cassette according to claim 68 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

71. A recombinant expression cassette according to claim 68 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

72. A recombinant expression cassette according to claim 65 in which the expression cassette comprises two or more regulatory elements derived from intron 3 of the PSM gene.

73. A recombinant expression cassette according to claim 65 in which the expression cassette comprises a dimer or higher multimer comprising two or more regulatory elements derived from intron 3 of the PSM gene.

74. A recombinant expression cassette according to claim 65 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

75. A recombinant expression cassette according to claim 74 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

76. A recombinant expression cassette according to claim 75 in which the promoter active in the prostate is a PSM promoter.

77. A recombinant expression cassette according to claim 65 in which the expression cassette further comprises a polyadenylation signal located downstream from and operably linked to the coding sequence or downstream from the insertion site.

78. A recombinant expression cassette according to claim 77 in which the polyadenylation signal is the SV40 polyadenylation signal or the bovine growth hormone polyadenylation signal.

79. An isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising

- (a) a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11, or
- (b) a nucleic acid sequence which hybridises under high stringency to the sequence defined in paragraph (a).

80. An isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising

- (a) a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11, or
- (b) a nucleic acid sequence which hybridises under high stringency to the sequence defined in paragraph (a).

81. A recombinant polynucleotide comprising an isolated nucleic acid molecule of claim 79.

82. A vector comprising an isolated nucleic acid molecule as claimed in claim 79.

83. A vector according to claim 82 which further comprises a gene encoding a selectable marker.

84. A vector according to claim 82 in which the vector is a human adenovirus Type 5 or ovine adenovirus.

85. A method for directing expression of a coding sequence in a cell, the method comprising introducing into the cell a recombinant expression cassette comprising at least one regulatory element derived from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the regulatory element and promoter direct expression of the coding sequence.

86. A method according to claim 85 in which the regulatory region is an enhancer element.

87. A method according to claim 86 in which the enhancer element comprises

(a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or

(b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

88. A method according to claim 86 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

89. A method according to claim 86 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

90. A method according to claim 85 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus

(RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

91. A method according to claim 90 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

92. A method according to claim 91 in which the promoter active in the prostate is a PSM promoter.

93. A method according to claim 85 in which the cell is selected from the group consisting of a prostate cell, a bladder cell, a breast cell or a vascular endothelial cell.

94. A method according to claim 85 in which the cell is a vascular endothelial cell.

95. A method for the treatment of cancer which method comprises administering to a subject a recombinant expression cassette comprising at least one regulatory element derived from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the regulatory element and promoter direct expression of the coding sequence.

96. A method according to claim 95 in which the regulatory region is an enhancer element.

97. A method according to claim 96 in which the enhancer element comprises

(a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or

(b) a nucleic acid sequence which hybridises under high stringency to a sequence defined in paragraph (a).

98. A method according to claim 96 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

99. A method according to claim 96 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

100. A method according to claim 95 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

101. A method according to claim 100 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

102. A method according to claim 101 in which the promoter active in the prostate is a PSM promoter.

103. A method according to claim 95 in which the cancer is selected from the group consisting of prostate cancer, bladder cancer and breast cancer.

104. A method according to claim 95 in which the cell is a vascular endothelial cell.

105. A method according to claim 95 in which the cancer is prostate cancer.